Axium MicroFX Coil for the Completing Endovascular Aneurysm Surgery Study (ACCESS)

A Prospective Evaluation of the Safety and Durability of Axium MicroFX PGLA Coils

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Summary

Recanalization of previously coiled aneurysms remains a major drawback of endovascular aneurysm therapy. We performed a prospective single arm trial to provide early initial data regarding the safety and angiographic durability of a new coil technology, the Axium MicroFX Polyglycolic/polylactic acid (PGLA) coil, which was designed to lower recanalization rates.

Fifteen patients (16 aneurysms) were prospectively enrolled. Demographic and peri-procedural data were collected. Angiographic images of the initial coil embolization and three to six month follow-up angiographic images underwent blinded evaluation.

Seven (47%) SAH and eight (53%) elective patients were enrolled. Blinded evaluation of the initial embolization demonstrated that 5/16 (31%) aneurysms achieved Raymond grade 1, 5/16 (31%) grade 2 and 6/16 (38%) grade 3. Three to six month angiography was obtained in 12/15 patients (80%); two patients expired (1 SAH, 1 elective) and one was lost to follow-up (SAH). All patients who underwent follow-up angiography had a mRS ≤1. Blinded evaluation of embolization demonstrated 7/13 aneurysms (54%) improved in Raymond grading, five (38%) were stable and one aneurysm (8%) worsened. One patient developed an asymptomatic peri-aneurysmal parent vessel stenosis.

Axium MicroFX coils appear to be safe, though the small number of patients in this series obviates comparative analysis with other series. Further studies are needed with more patients to compare the angiographic durability of Axium MicroFX coils to other coils.

Introduction

Aneurysmal recurrence due to recanalization remains a major disadvantage of endovascular coil embolization. Several investigators have reported recanalization rates of more than 30 percent after coil embolization [1-4]. Additionally, recent prospective adjudicated data have demonstrated similarly high recanalization rates [1,5-7]. In an effort to ameliorate this limitation, neuroendovascular companies continue to present new coil technologies, touting improved functionality, and concomitantly charging an additional price premium. However, such marketing comes with little or no prospective data to evaluate such claims – and when such data is provided it is typically many years after a given technology is introduced [1,5-7]. In an effort to counter this trend Covidien-ev3 Neuro Division (Irvine, CA) agreed to fund a completely independent, university run, prospective single arm trial to provide early initial data regarding the safety and angiographic du-

technology, the Axium MicroFX Polyglycolic/polylactic acid (PGLA) coil. While the funding to perform this study was provided by Covidien-ev3 Neuro Division, all data collection, analysis, and evaluation was performed independently without industry input or oversight.

Material and Methods

ACCESS was designed as a single-institution, prospective, observational trial with consecutive enrollment of all patients meeting inclusion and exclusion criteria in order to evaluate the initial safety and efficacy of Axium MicroFX coils. The institutional review board of the University of Florida approved this study, and consents were obtained from patients or their appropriate surrogate.

Inclusion criteria consisted of: confirmed diagnosis of one or more ruptured or unruptured aneurysms, an aneurysm diameter of ≤10 mm and an age range between 18 and 90 years. Patients were excluded if the aneurysm had been previously treated, was AVM-related or caused by a dissection. Patients were also excluded if they were part of another trial, had a condition that would preclude the conduct of protocol follow-up or if, prior to opening the Axium coil or any attempted placement, it was determined on angiography that the aneurysm anatomy was considered to be unsafe/unfavorable for placement of Axium coils by the practicing physician. Only aneurysms ≤10 mm were used secondary to the Axium MicroFX coil line only being available up to the 10 mm size at the initiation, and through the majority of the course, of the study. According to the discretion of the treating physician alternate bare platinum coils were allowed, however a goal of 90% total coil length of Axium MicroFX was encouraged.

Coiling angiograms and follow-up angiograms were performed with a heparinized saline flush. A separate heparin bolus was only given after obtaining groin access for coiling of unruptured aneurysms. The initial coiling result was determined with an angiogram at the end of each coiling procedure, also in patients who had received a heparin bolus.

The primary endpoint was blinded evaluation of anatomic occlusion of the aneurysm immediately post-procedure. Secondary endpoints evaluated the safety (as recorded by all complications, and patients discharge and three to six months mRS), technical efficacy (rate of unsuccessful detachment), and the stability of embolization (by a blinded interventionalist). Obliteration and stability of embolization was evaluated with the Raymond scale. Raymond grade 1 was reserved for aneurysms which were completely obliterated, Raymond grade 2 described aneurysms which had a small neck remnant or dog ear. Raymond grade 3 aneurysms presented with residual filling of the aneurysm fundus or dome. Patients were scheduled to undergo follow-up angiography between three and six months after the initial procedure according to their convenience, as is standard of care at our institution. The evaluation was considered complete once patients had completed their three to six month clinical and angiographic follow-up.

For the purposes of consistency the blinded angiographic reviewer was provided with a series of angiographic images that included AP, lateral and magnified working angle projections of the aneurysm before coiling, which were paired with post-embolization images that were from either immediately following the initial coiling or from the angiographic follow-up angiography. The paired images were de-identified and underwent a block randomization to minimize the reviewer's ability to extrapolate across the various pairs of images. Batches of randomized images were sent to an extra-institutional reviewer for grading of Raymond grade occlusion. The reviewer was therefore blinded to whether he was assessing the immediate post-coiling angiogram or the follow-up angiogram.

Results from the blinded Raymond grading were analyzed for significance with a two-tailed Wilcoxon matched-pairs signed-ranks test. Significance was set at $p < 0.05$.

Results

Fifteen patients underwent treatment of 16 aneurysms. The majority of study participants were female (87%). Average age at the time of treatment was 58±14 years. Most patients had a history of smoking (87%) or were smokers at the time of diagnosis (73%). Fifty percent of patients who underwent follow-up angiography had continued smoking against medical advice. The most common other comorbidity was hypertension which was present in 60% of study participants, followed by hyperlipidemia (33%). Forty-seven percent (n=7) of patients present-

ed with ruptured aneurysms, the most common presentation being Hunt & Hess grade 3 (57%; Table 1). The most common location for the aneurysms treated was the ACOM location (31%), followed by PCOM and paraclinoid ICA (both 19%).

Non-Axium MicroFX coils were rarely used (six of 58 total coils). Reasons for non-Axium MicroFX included: the desire to use a "half-size" (e.g., 3.5 mm coils) in small aneurysms for which there was no Axium MicroFX equivalent (4 cases) or, secondary to shear timing of enrollment, the desired "whole" size was simply out of stock and not replenished at the time of the procedure (two cases). In total, nine of 16 aneurysms (56%) were treated entirely with Axium MicroFX coils, while the other aneurysms each included one non-Axium coil. Ninety-four percent of total coil length (540 of 576.5 cm) used across the cohort consisted of Axium MicroFX coils. The average percentage of Axium MicroFX coils used per patient was 92±12%. Seven aneurysms (44%) were treated with stent-assistance.

All elective coiling patients were discharged home post-operative day 1 with a mRS of 0. All but one of these patients remained mRS 0 throughout the study period. The exception was a patient who had undergone stent-assisted elective coiling of a 9 mm left MCA aneurysm without complication, but did not respond to attempted follow-up efforts. After sending a certified letter it was learned that 121 days following the embolization the patient was admitted to an outside hospital with a severe exacerbation of his known COPD. He had stopped his Plavix one month prior to this hospitalization against medical advice (our standard of care is to continue double antiplatelet therapy until follow-up imaging is obtained) and changed his aspirin dose from 325 mg to 81 mg, also against medical advice. A head CT was performed

Table 1

Patient No.	Presentation	Age	Maximal Size of Aneurysm	Stenting	Total Coil length	Total Packing density	Post-coil blinded Raymond	Follow-up blinded Raymond	Clinical outcome (mRS)
1	Unruptured	51	7.4 mm	Enterprise 4.5×22 mm	35 cm	9.19%	3	1	0
2	Unruptured	62	9 mm	Enterprise 4.5×22 mm	60 cm	11.98%	2	N/a	6
3	Unruptured	53	9.5 mm	Enterprise 4.5×22 mm	59 cm	12.32%	1	1	0
4	Unruptured	67	8.5 mm	–	44 cm	7.8%	1	1	0
5	Unruptured	54	7 mm	Enterprise 4.5×20 mm	20 cm	7.15%	3	1	0
6	Unruptured	68	9.4 mm	–	38 cm	7.85%	3	1	0
7	Unruptured	62	7 mm and 7 mm	Enterprise 4.5×20 mm	22 cm and 24 cm	12.44% and 15.22%	First Aneurysm: 3 Second Aneurysm: 3	First Aneurysm: 1 Second Aneurysm: 2	0
8	Unruptured	58	9.1 mm	Enterprise 4.5×28 mm	65 cm	10.04%	3	1	0
9	H&H 1, Fisher 2	47	6.5 mm	–	15 cm	7.58%	1	1	1
10	H&H 3, Fisher 3	55	7 mm	–	60 cm	16.88%	2	2	1
11	H&H 3, Fisher 3/4	85	7 mm	–	18 cm	12.14%	1	N/a	6
12	H&H 3, Fisher 3	44	6 mm	–	29 cm	8.13%	2	1	1
13	H&H 1, Fisher 3	84	7.8 mm	–	35 cm	15.23%	2	N/a	Lost to follow–up
14	H&H 1, Fisher 1	31	8 mm	–	27 cm	13.2%	1	2	1
15	H&H: 3, Fisher: 3	46	8 mm	–	25.5 cm	5.48%	2	2	1

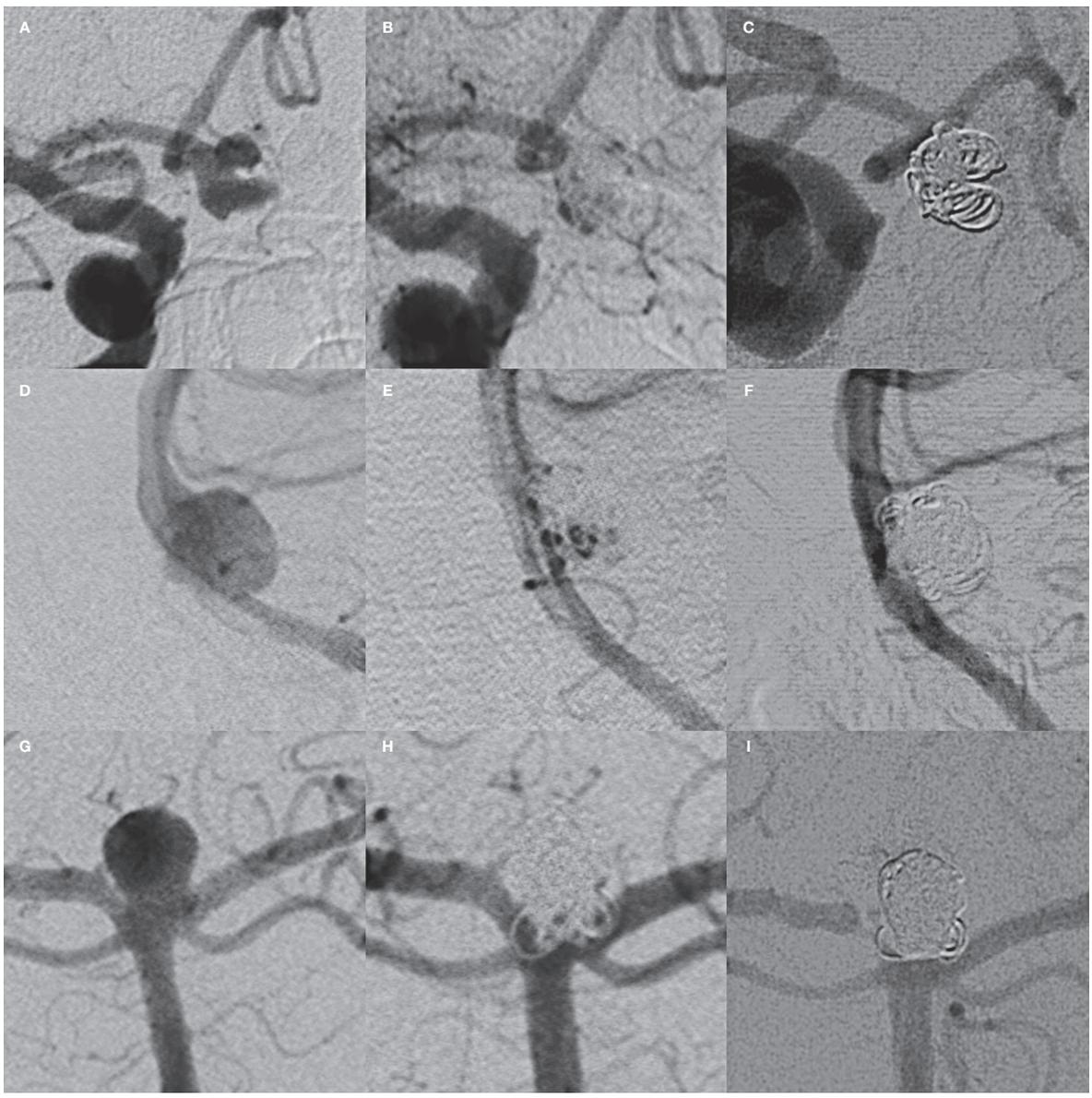

Figure 1 Coiling of an unruptured ACOM aneurysm (A) resulted initially in a Raymond grade 3 aneurysmal occlusion (B). Follow-up angiography 3 months after coiling showed progressive thrombosis to a Raymond grade 1 (C). Another patient with an unruptured basilar trunk aneurysm (D) underwent stent-assisted coiling resulting in a Raymond grade 3 (E) which also progressed to a Raymond grade 1 on follow-up angiography 3 months later (F). It is possible that heparin reversal contributed to the progressive thrombosis in the treatment of these unruptured aneurysms. One patient with a ruptured basilar tip aneurysm (G) underwent coiling of her aneurysm (H). The aneurysm showed progressive thrombosis on a follow-up angiogram 7.5 months later; she also developed a right PCA stenosis at the site of herniation of one coil loop (I).

more than six hours after onset of his exacerbation (immediately following intubation) that was negative for any abnormality. The patient progressed to sepsis and severe hypotension (prolonged SBPs in the 80's). He was sedated for two days and treated with antibiotics. A head CT repeated three days after his admission demonstrated a new large left MCA infarct. After a discussion with his wife, care was withdrawn (mRS=6).

The majority of patients who suffered from subarachnoid hemorrhage were discharged with a mRS of 1 (57%). One of these patients needed shunting for persistent hydrocephalus (7%).

Two patients (13%) were discharged with a mRS of 4. One of these mRS of 4 patients had developed clinically significant vasospasm requiring treatment with intra-arterial verapamil and had respiratory failure requiring tracheostomy. However, at her delayed follow-up (6.5 months) she had improved to a mRS of 1. The second mRS 4 patient was an 84-year-old woman who was admitted with a Hunt & Hess grade 1, Fisher 3 subarachnoid hemorrhage and treated with Axium MicroFX coils for a ruptured left PCOM aneurysm. She tolerated the procedure well, however, approximately 40 minutes after the procedure, she developed acute right-sided weakness in the intensive care unit. The patient immediately returned to the angiography suite and was found to have a partially-occlusive thrombus in her left cervical internal carotid artery which was treated with 7 mg intra-arterial ReoPro as well as placement of a stent to pin the clot against the vessel wall. The patient was also started on IV ReoPro, and maintained on Plavix and Aspirin. Despite these attempts, the patient continued to have severe (2/5) right-sided weakness after the procedure. Immediate CT imaging was negative, however, delayed imaging demonstrated an apparent left middle cerebral artery territory embolic infarct. She was discharged to a rehabilitation facility. Her family would not respond to multiple attempts at further follow-up, including a certified letter. One 85-year old patient died following treatment of a ruptured ACOM aneurysm. She presented as a Hunt & Hess 3, Fisher 3 subarachnoid hemorrhage and had her aneurysm 100% occluded without complication. She maintained good neurological status, however she had strong DNI wishes and on post-coiling day five she suffered severe respiratory decline. Initially, she voluntarily rescinded her DNI, however after two days without improvement she was terminally extubated (mRS=6). All outcome data are listed in Table 1.

Blinded Raymond grading of all aneurysms after initial coiling demonstrated that five out of 16 aneurysms were considered a Raymond grade 1 (31%), another five out of 16 were Raymond grade 2 (31%), and six out of 16 were Raymond grade 3 (38%).

Follow-up angiography was performed in 12/15 patients (80%). At the time of follow-up, all patients with unruptured aneurysms presented with a mRS of 0 (7/7; 100%), and all patients with initially ruptured aneurysms presented with a mRS of 1 (5/5; 100%). All were intact to a standard neurological examination. Reasons for mRS 1 status included fatigue (n=2), memory problems (n=2), depression, balance problems and diplopia (each n=1).

Blinded Raymond grading of aneurysm embolization at follow-up angiography revealed 9/13 (69%) were Raymond 1 and 4/13 (31%) were Raymond 2. No aneurysms remained Raymond 3. Initial Raymond scores for those patients with follow-up were worse than those of the total cohort (Raymond 1 = 31%; Raymond 2 = 23%; Raymond 3 = 46%). Overall, 7/13 (54%) aneurysms demonstrated an improvement in Raymond grading on follow-up angiogram, 5/13 (38%) of aneurysms were stable, and one aneurysm (8%) worsened on its Raymond grade. Examples of progressive thrombosis can be found in Figure 1. Statistical analysis showed that the improvement in blinded Raymond grading was significant (p=0.023).

One patient was determined to have a new stenosis of her right PCA just distal to her embolized basilar tip aneurysm (Figure 1G-I). This stenosis was asymptomatic, but did reach 50%. The patient did have a single coil "tail" that had herniated into that PCA during the original embolization. Also of note, the patient was not maintained on any anti-platelet medication following her embolization.

Discussion

We present a small single arm prospective evaluation of the safety and durability of Axium MicroFX PGLA coils, with blinded radiologic assessment. Axium MicroFX PGLA coils proved to be durable on follow-up angiography and it appears there may be a pro-thrombogenic component that promotes the progressive occlusion of incompletely embolized aneurysms. Observed progressive occlusions may merely be a phenomenon of heparin reversal in the unruptured aneurysm patient cohort since post-coiling angiograms were done immediately after the procedure in which a heparin bolus had been given. However, a case of progressive occlusion was also seen in the cohort of ruptured aneurysm patients who did not receive a heparin bolus (Table 1).

We observed a statistically significant improvement in blinded Raymond grading scores of aneurysms on follow-up angiography, performed on average 121 days (approximately four months) after the initial procedure. How-

ever, it should be stressed that although the rigors of mathematical analysis were met, there is much potential for bias in such a small (n=16) and heterogeneous sample size. Therefore, a larger follow-up study is certainly required before any definitive conclusions can be drawn.

Only one aneurysm (8%) received a worse Raymond score on follow-up angiography. Interestingly, this progressive occlusion and low recanalization rate existed despite 50% of our patients continuing to smoke against medical advice. Seven out of 16 aneurysms were coiled with stent-assistance, which has been suggested to aid in the prevention of aneurysmal recanalization, however, we also observed progressive aneurysmal occlusion on follow-up angiography in aneurysms which were not coiled with stent-assistance. Figure 1A-C demonstrates an example of such cases. It should also be noted that the initial Raymond scores for those patients with follow-up were worse than those of the total cohort (Raymond 1 = 31%; Raymond 2 = 23%; Raymond 3 = 46%), suggesting that the observed improvement was not secondary to patient mortality or the one patient who was lost to follow-up.

Progressive autologous occlusion of aneurysms by adjunctive materials in the coil mass is not a new concept. Neurointerventionalists remain concerned about aneurysmal recanalization after coil embolization, despite published re-bleeding rates being quite low after endovascular treatment. Different technologies have been designed to oppose aneurysmal recanalization such as coils coated with a hydrogel. HydroCoils® (Microvention, Aliso Viejo, CA, USA) were found to lower major recurrences by 8.6% compared to bare platinum coils, however, the rate of major recurrence in the HydroCoil® arm remained 27% (blinded evaluation). Unfortunately, there also appears to be an approximately fivefold increase in the rate of hydrocephalus in non-recently-ruptured aneurysms. This increase was not statistically significant, but is certainly worth considering. We would strongly stress that the above mentioned HydroCoil® data comes from an outstanding, prospective, randomized trial of over 400 patients and as such are certainly in no way directly comparable to our prospective, but small, single arm trial. We present these previously published data only as an example of current standards, both in quality patient care and scientific investigation. The early Axium MicroFX data presented herein is meant to provide our community with high quality, prospective, adjudicated early feedback, which will be helpful in the planning stages of future studies.

Coils containing polyglycolic/polylactic acid have also been introduced to the endovascular community in recent years, with the intent to increase aneurysm occlusion durability and enhance progressive intra-aneurysmal thrombosis. The Cerecyte® coil (Micrus Endovascular, San Jose, CA, USA) has polyglycolic acid (PGA) running through the lumen of the primary wind; the Matrix® detachable coil (Boston Scientific/Target, Fremont, CA, USA) is coated with polyglycolic acid and polylactic acid. One important difference of the Axium MicroFX coil in comparison with other PGLA/PGA coils lies in its microfilament technology (Lattice FX technology) which is hypothesized to provide for significant intra-aneurysmal hemodynamic effects to complement biologic activity that may be occurring as a result of the PGLA.

Several investigators have examined the clinical properties of Matrix® detachable coils. Progressive thrombosis was found by Fiorella et al. in 26.8% of aneurysms after an average follow-up time of 6.9 months, however, the recanalization rate was observed to remain high (36.6%). Niimi et al. reported recanalization rates of 54.3% with the Matrix® coil after an average follow-up time of 12.2 months. Pierot et al. found progressive thrombosis in 30% and recanalization in 25.7% of patients treated with Matrix® coils after 14 months. They concluded that the efficacy of the Matrix® coil to prevent aneurysmal recanalization was not demonstrated. Only Murayama et al. found an improvement in recanalization rates with Matrix® coils compared to bare platinum coils. More recently, the preliminary findings of the MAPS (Matrix® and Platinum Science) trial were presented at the 2011 SNIS Annual Meeting, and those results demonstrated no significant benefit in recanalization with Matrix® coils versus platinum coils.

Cerecyte® coils were found to have lower than expected recanalization rates across numerous single arm or non-randomized investigations. In a retrospective study of Cerecyte® coils, Geyik et al. found that further thrombosis to Raymond grade 1 on follow-up angiography occurred in 77.3% of aneurysms after a mean follow-up period of 10.5 months. Recanalization to a Raymond grade 2 was found in 7% and to grade 3 in 1.8% of patients. Low recur-

rence rates were also reported by Veznedaroglu and coworkers. Butteriss et al. found progressive thrombosis in only 8.8% of aneurysms and the highest recanalization rate (20.5%) after six months. Castro et al. reported a recurrence rate of 16.7% after six months. Unfortunately, a prospective randomized trial to evaluate the potential utility of the Cerecyte® coil as compared to bare platinum found no benefit to Cerecyte®. Our results with the Axium MicroFX PGLA coil are certainly exciting and compare well to the early single arm/non-randomized Cerecyte® data, and doubtless the same potential lack of confirmation in a randomized trial is a possibility for this technology. However, unlike the early Cerecyte® data, this study was both prospective and blinded; whereas none of the early single-arm Cerecyte® studies were both prospective and blinded. Whether this results in any difference in the predictive value of this study remains to be seen. Perhaps a more concerning limitation of these data is the overall small number of cases, and certainly a larger prospective series is warranted before any data considerations are used to influence clinical practice.

We observed no clinical complications directly attributable to the Axium MicroFX PGLA coils. The only case where a possible connection might be made (the one stent-assisted coiling patient who died four months after the procedure following a left MCA infarction in the setting of non-compliance with his ASA and Plavix medication, sepsis and hypotension) had demonstrated a Raymond grade 2 aneurysmal occlusion and no coils were evident in the parent vessel. It appears likely that the patient's infarct was most likely secondary to some degree of instent stenosis or thrombosis brought about by medication non-compliance and exacerbated by the patient's severe hypotension and sepsis. However, some potential for contribution to this injury by the coils cannot be entirely ruled out. The only other death was secondary to withdrawal of care in an 85-year-old patient secondary to respiratory insufficiency, without neurologic worsening, that occurred five days post-coiling. This patient had not received general anesthesia during coiling, however, it is possible that the increased fluid load from the heparinized saline flush during coiling contributed to the eventual respiratory decline. The only further significant morbidity was a stroke in an 84-year-old subarachnoid hemorrhage patient who developed a thrombus in her left cervical internal carotid artery after coiling and who had no thrombus in the vicinity of her coiled left PCOM aneurysm. It appears that her thrombus developed due to a small tear in the intima of the cervical internal carotid artery possibly due to the guide catheter, but in no way attributable to the coils themselves (which were anatomically far removed from, and distal to, the thrombus). This patient was confirmed alive at a nursing facility, however, repeated requests issued to the family, including a certified letter, were unable to generate permission to obtain medical details from either the family or the facility.

We also observed one radiographic complication that did not result in clinical consequences. A parent vessel showed stenosis on follow-up angiography which was in proximity to a single herniated tail of PGLA coil following initial coil embolization (see Figure 1G-I). This stenosis was not observed on a one-week post treatment angiogram that was performed to evaluate for vasospasm, so there may have been a value in adding some level of anti-platelet therapy after the acute SAH period had passed, however, as of yet, this is pure speculation.

Conclusion

Axium MicroFX PGLA coils appear, in this small prospective blinded study, to be safe enough to proceed with further larger trials. Studies examining durability with a larger patient cohort and longer follow-up times are needed to confirm our initial exciting results.

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